THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL T. JACOBS, RONALD F. BERRY
and TOBY A. SOTO

Appeal No. 1996-0857
Application No. 08/120,303

ON BRIEF

Before JOHN D. SMITH, GARRIS, and SPIEGEL, *Administrative Patent Judges.*

SPIEGEL, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 11 and 17 through 20. Claims 12 through 16, 21 and 22, the only other claims pending in this application, have been indicated as allowable by the examiner.[1] Claims 11, 17 and 20 are illustrative and read as follows:

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[1]See the advisory action mailed July 21, 1994 (Paper No. 23).

11. A device *for delivering antimicrobial vapor* to the lumen of an article during solution vapor sterilization, said device comprising

a vessel for containing an antimicrobial solution and having an opening therein, and

means for connecting said opening of said vessel to said lumen

said vessel being closed to the ambient atmosphere except through *such* opening

said vessel containing a known quantity of antimicrobial solution for vapor formation. [Emphasis added.]

17. A device *for delivering antimicrobial vapor* to the lumen of an article during solution vapor sterilization, said device comprising

a vessel for containing an antimicrobial solution and having an opening therein, and

means for connecting said opening of said vessel to said lumen

said vessel being closed to the ambient atmosphere except through *such* opening

said vessel containing a known quantity of antimicrobial solution for vapor formation

wherein said vessel includes a second opening for releasably attaching a cartridge containing said known quantity of antimicrobial solution. [Emphasis added.]

20. A device for enhancing solution vapor sterilization of the lumen of a medical instrument, said device comprising

a vessel for containing an antimicrobial solution, and

a means for connecting said vessel to the end of said lumen to provide antimicrobial vapor directly to the lumen during the solution vapor sterilization

said device being sealed from the ambient atmosphere except through said means for connecting and containing a known quantity of antimicrobial solution. [Emphasis added.]

The examiner relies upon the following references of record:

Wyka	3,371,985	Mar. 5, 1968
Engel (Engel '985)	3,688,985	Sep. 5, 1972
Engel (Engel '434)	3,730,434	May 1, 1973
Al-Sioufi	4,675,159	Jun. 23, 1987

Fisher Scientific 1983 Catalog (Fisher), pages 46C and 47C.

ISSUES[2]

I. Claim 17 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite in failing to clearly set forth the positioning or structural relationship between the second opening and the vessel. II. Claims 11, 19 and 20 stand rejected under 35 U.S.C. § 102 as being anticipated by Al-Sioufi. III. Claims 11, 19 and 20 stand rejected under 35 U.S.C. § 102 as anticipated by or, in the alternative under 35 U.S.C. § 103 as being unpatentable over Fisher. IV. Claims 11 and 18-20 stand rejected under 35 U.S.C. § 102 as anticipated by or, in the alternative under 35 U.S.C. § 103 as being unpatentable over Engel '434. V. Claims 11 and 18-20 stand rejected under 35 U.S.C. § 103 as being unpatentable over Wyka.

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[2] The amendment filed June 17, 1994 (Paper No. 21) amending claims 12, 14, 16, 17 and 21 was entered by the examiner in the advisory action mailed July 21, 1994 (Paper No. 23) and (i) overcame the final rejection of claim 17 under 35 U.S.C. § 112, second paragraph, as indefinite as to the relationship between the "measured aliquot of antimicrobial solution" recited in claim 17 and the "known quantity of antimicrobial solution" recited in claim 11, (ii) overcame the final rejection of claim 17 under 35 U.S.C. § 112, fourth paragraph, as not further limiting the subject matter of claim 11, and (iii) overcame the objection to claims 12-16 and 21-22 as being dependent upon a rejected base claim. According to the advisory action (Paper No. 23), "claim 17 is still unclear as to the openings and will be rejected under 112, second paragraph on Appeal."

We affirm-in-part and institute a new ground of rejection.

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's answer (Paper No. 26, mailed March 9, 1995) and supplemental answer (Paper No. 28, mailed August 22, 1995) for the examiner's reasoning in support of the rejections, and to appellants' brief (Paper No. 23½, filed December 19, 1994) and reply brief (Paper No. 27, filed May 8, 1995) for the appellants' arguments thereagainst.

According to appellants, the claims are grouped as follows: (1) claims 11, 18 and 19, (2) claim 17 and (3) claim 20 (brief, p. 3, ll. 26-27). Therefore, we decide this appeal on the basis of claims 11, 17 and 20. 37 C.F.R. § 1.192(c)(5)(1993).

THE INVENTION

The claimed invention is directed to a device for vapor sterilization of articles having long, narrow lumens, e.g., an endoscope. The device comprises (a) a vessel having a first opening and containing a known amount of a vaporizable liquid antimicrobial either directly therein or indirectly (i.e., the vessel may be provided with a second opening for attaching a disposable cartridge containing the antimicrobial solution thereto) and (b) a means for connecting the vessel to the lumen of the article. When the article with the device connected thereto is disposed in a sterilization chamber and the pressure in the chamber is reduced, antimicrobial

vapor is generated from the liquid antimicrobial within the vessel and flows directly into the lumen. [Specification, p. 2, ll. 13-26; p. 3, ll. 7-17; p. 4, ll. 24-26; p. 7, ll. 26-34.]

OPINION

I. Claim interpretation

A. background

Our appellate reviewing court stated in *Panduit Corp. v. Dennison Mfg. Co.,* 810 F.2d 1561, 1567-68, 1 USPQ2d 1593, 1597 (Fed. Cir.), *cert. denied,* 481 U.S. 1052 (1987):

> Analysis begins with a key legal question -- *what* is the invention *claimed*? Courts are required to view the claimed invention *as a whole*. 35 U.S.C. § 103. Claim interpretation, in light of the specification, claim language, other claims, and prosecution history, is a matter of law and will normally control the remainder of the decisional process. [Footnote omitted.]

As set forth in *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989):

> During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow. When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. *See In re Prater*, 415 F.2d 1393, 1404-05, 56 CCPA 1381, 162 USPQ 541, 550-51 (1969) (before the application is granted, there is no reason to read into the claim the limitations of the specification). The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. ... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

35 U.S.C. § 112, sixth paragraph, provides explicit guidance for interpreting terms written in a "means-plus-function" format.

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Therefore, our initial inquiry is three-fold. First, is claim 11, 17 and/or 20 a means-plus-function claim(s). Second, if the claim is a means-plus-function claim, what is the "function" that the claim element is required to perform. Third, if the claim is a means-plus-function claim, what is the "corresponding structure" identified in the specification that carries out the claimed function.

B. claims 11, 17 and 20 are written in means-plus-function format

First, claims 11, 17 and 20 all recite a claim element in purely functional terms, without the additional recitation of specific structure or materials for performing that function. Claims 11 and 17 both recite a "means for connecting said opening of said vessel to said lumen," while claim 20 recites a "means for connecting said vessel to the end of said lumen."

C. claimed function required to be performed by the means

Second, claims 11 and 17 require the recited "means" to connect the opening of the vessel to the lumen of an article to deliver the antimicrobial vapor to the lumen of the article, while claim 20 requires the recited "means" to connect the vessel to the end of the lumen to provide antimicrobial vapor directly to the lumen of a medical instrument during solution vapor sterilization of the medical instrument.

D. corresponding structure disclosed for carrying out the claimed function

Finally, having identified the required function, we must next identify the "corresponding structure, material, or acts described in the specification ...," (§ 112, ¶6) that carry out that function. A structure disclosed in the specification only constitutes a "corresponding structure" if the specification clearly links or associates that structure to the function recited in the claim. *Kahn v. General Motors Corp.*, 135 F.3d 1472, 1476, 45 USPQ2d 1608, 1611 (Fed. Cir. 1998).

1. claim differentiation

> There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant.

Tandon Crop. v. United States International Trade Commission, 831 F.2d 1017, 1023, 4 USPQ2d 1283, 1288 (Fed. Cir. 1987). Thus, a "means for connecting said opening of said vessel to said lumen" and a "means for connecting said vessel to the end of said lumen to provide antimicrobial vapor directly to the lumen during the solution vapor sterilization" are presumed to have different meanings and scopes. This presumption is strengthened by the fact that claims 11 and 17, which recite a "means for connecting said opening of said vessel to said lumen," are closed to ambient atmosphere "except through *such* opening" (emphasis added), while claim 20, which recites a "means for connecting said vessel to the end of said lumen," is closed to ambient atmosphere "except through said means for connecting."

2. *disclosed corresponding structure for a "means for connecting said vessel to the end of said lumen"*

The specification discloses that the means of connecting the vessel to the lumen of the instrument can be

(1) a piece of firm but flexible tubing of such diameter that one end of the tubing may be inserted in or disposed about the opening of the vessel, while the other end is inserted in or disposed about the lumen so as to *securely join* the two (p. 3, ll. 17-24);

(2) an expandable sheath, one end of which is *securely attached* about the opening in the vessel, while the other end comprises an elastic ring for making a releasable attachment about the end of an article having the lumen (p. 4, ll. 5-10; p. 10, ll. 28-32);

(3) a flexible bushing within the opening of the vessel which *provides resistance to the withdrawal* of a tube inserted therethrough (p. 4, ll. 16-18; p. 11, ll. 25-35);

(4) a drawstring disposed about the opening of a pouch-type vessel, whereby a *firm fastening* may be made to a tube inserted within the vessel (p. 4, ll. 29-31; p. 17, ll. 4-6); or

(5) a syringe *attached* to the end of the tube/article *per se* (p. 8, l. 15 - p. 10, l. 22).

3. *no disclosed corresponding structure for a "means for connecting said opening of said vessel to said lumen*

Neither appellants nor the examiner have pointed out, and we do not find, where the specification discloses a corresponding structure for a "means for connecting said opening of said vessel to said lumen" and clearly links or associates that structure to the function recited in claims 11 and 17.

II. New ground of rejection under 37 C.F.R. § 1.196(b)

> Although paragraph six statutorily provides that one may use means-plus-function language in a claim, one is still subject to the requirement that a claim "particularly point out and distinctly claim" the invention. Therefore, if one employs means-plus-function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by the language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.

In re Donaldson Co., Inc., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994).

In view of the lack of a disclosed "corresponding structure" for connecting the opening of the vessel to the lumen of an article to deliver antimicrobial vapor to the lumen and of the principle of claim differentiation discussed above, neither an actual means nor means that are "equivalent" to the actual means can be determined. Therefore, claims 11 and 17-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

III. Prior art rejections of record

A. Claim 11

While we might speculate as to what is meant by the claim language, our uncertainty provides us with no proper basis for making the comparison between that which is claimed and the prior art as we are obliged to do. Rejections under 35 U.S.C. § 102 and § 103 should not be based upon "considerable speculation as to the meaning of the terms employed and assumptions as to the scope of the claims." *In re Steele*, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962). When no reasonably definite meaning can be ascribed to certain terms in a claim, the

subject matter does not become obvious, but rather the claim becomes indefinite. *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Accordingly, we are constrained to reverse, *pro forma*, the examiner's rejections of claim 11 and its dependent claims 18 and 19 under 35 U.S.C. § 102(b) and § 103. We hasten to add that this is a procedural reversal rather than one based upon the merits of the section 102(b) and section 103 rejections.

B. Claim 20

1. as anticipated by Al-Sioufi or
as anticipated by or, alternatively, as being unpatentable over Fisher or Engel '434

Al-Sioufi discloses a vessel **20** having a single opening, containing a known amount of glutaraldehyde (i.e., liquid antimicrobial solution) predisposed therein, and closed at the opening with an elastomeric stopper **21** (Figure 1; c. 7, ll. 23-54). Fisher discloses capped bottles containing solutions of acids and bases of known concentrations (pp. 46C-47C). Engel '434 discloses a vessel **11** having a single opening **14**, containing a wick **16** impregnated with a sanitizer (i.e., liquid antimicrobial solution) (Figure 2; c. 3, ll. 1-59).

According to the examiner, either the single opening shown in Al-Sioufi or the single opening of the container of Fisher Scientific would have "inherently provided the presently recited capability of connecting the opening of the vessel to a lumen by either insertion of the lumen within the opening, analogous to the attachment of the cap (21), or by insertion of the vessel opening into the lumen" (answer, p. 6, ll. 24-29; p. 7, ll. 11-14). According to the examiner, the volatile material impregnated in the wick of Engel '434 is either provided in a

known quantity and concentration or, alternatively, it would have been obvious to determine the actual quantity of impregnated material to ensure uniformity and quality control assurance during manufacture of the device of Engel '434 (answer, p. 7, l. 23 - p. 8, l. 14).

We do not agree with this reasoning. In light of the sixth paragraph of 35 U.S.C. § 112, the single opening of Al-Sioufi or Fisher is not corresponding structure to, or the equivalent of, the means disclosed in the specification. The single opening of either Al-Sioufi or Fisher fails to provide the secure attachment necessary to provide antimicrobial vapor directly to the lumen. Furthermore, the examiner does not point out, and we do not find, where Engel '434 discloses or suggests the claimed means for connecting the vessel to the end of a lumen. Failure to provide means which provides the secure attachment necessary for delivering the antimicrobial vapor into the lumen precludes a finding of obviousness over the disclosure of Al-Sioufi, Fisher or Engel '434. Therefore, these rejections of claim 20 are reversed.

2. as being unpatentable over Wyka

Wyka discloses a vaporizer device comprising a vessel **1** having a replaceable disinfectant-crystal-containing-cartridge **66** and connecting means, i.e., conduits **10** and **12**.

Appellants argue not only that Wyka does not disclose or suggest means for connecting a vessel to the end of a lumen to provide antimicrobial vapor directly to the lumen during solution vapor sterilization (brief, p. 8, ll. 6-10), but also that Wyka's device is not attached to any lumen (brief, p. 8, ll. 30-31). However, we agree with the examiner that the hoses or "conduits" themselves would have constituted lumen and, therefore, Wyka does disclose an equivalent

means to an actual means disclosed in the specification, i.e., a syringe *attached* to the end of the tube/article *per se* (specification, p. 8, l. 15 - p. 10, l. 22).

Appellants argue that Wyka's device is not limited to being open to the ambient atmosphere only through its hoses **10** and **12**, but is also open through hose **6** (brief, p. 9, ll. 3-10). However, when conduits **10** and **12** are attached to vessel **1**, Wyka's unidirectional valve **82** would have occluded the opening at hose **6**, while spring biased valve **60** would have provided the only opening to ambient atmosphere via attached conduits **10** and **12**. Therefore, this argument is not convincing.

Appellants concede that "[i]t is accepted that the sublimation of a solid substance to form a sterilizing vapor and the vaporization of the antimicrobial liquid called for in Claim 11 are equivalents" (brief, p. 6, ll. 29-31). Therefore, appellants apparently also concede that it would have been obvious to modify Wyka by providing solution-containing porous solids instead of crystals which sublime to form the disinfecting vapor as argued by the examiner (see the final Office action mailed December 16, 1983, Paper No. 18, p. 3, ll. 20-29).

Arguments based on the intended use of the claimed device (brief, p. 8, ll. 10-12), are not persuasive where, as here, it is the device which is being claimed, the prior art device satisfies the structural limitations of the claimed device, except for an apparently conceded equivalent source of antimicrobial vapor. The antimicrobial in the prior art device is in solid form, i.e., is a crystal, whereas the antimicrobial in the claimed device is in liquid form, i.e., is a solid substrate

impregnated with a liquid, and appellants have apparently conceded that using antimicrobials in liquid form or in solid form for vapor sterilization are equivalents as noted above.

For the above reasons, the rejection of claim 20 as being obvious over Wyka is sustained.

IV. Non-prior art based rejections of record

According to the examiner, claim 17 "fails to clearly set forth the positioning or structural relationship between the second opening and the vessel" (answer, p. 4, ll. 1-3) and "raises an ambiguity as to whether or not the antimicrobial solution is contained within the vessel as an element of the claimed invention or, alternatively, is contained in a separate cartridge which is not an element of the claimed invention" (answer, p. 4, ll. 13-17). This rejection is not predicated on the "means for connecting said opening of said vessel to said lumen" recited in claim 17. Thus, we may reach the merits of this rejection without engaging in any of the speculation raised by the meaning of that term.

According to appellants, claim 17 "relates to the structures shown in Figure 1 and Figure 2A" (brief, p. 4, ll. 15-16).

However, when we turn to Figures 1 and 2A of appellants' specification, the matter does not appear to be so clear-cut or straight forward. Device **10** in Figure 1 does not comprise a "cartridge" containing an antimicrobial solution or a vessel **14** having a "second opening." Similarly, vessel **34** in Figure 2A, which must be interpreted in light of Figure 2 (see specification, p. 12, ll. 8-15, i.e., Figure 2A is "a variation in the design of the device of Fig. 2")

has two openings **32** and **46**, but it does not contain an antimicrobial solution. Thus, it appears that various elements of Figures 1 and 2A are being arbitrarily "related" to the device of claim 17, using elemental designations not found in either the specification or the claim. For example, appellants refer to "a separate vial indicated as 14 in Figure 1 and 47 in Figure 2A which vial contains the antimicrobial solution" (brief, p. 4, ll. 27-28). However, claim 17 does not recite "a vial," element 14 in Figure 1 is the "vessel" recited in claim 17 and element 47 in Figure 2A is the "cartridge" recited in claim 17. Thus, we find that one having ordinary skill in the art would have difficulty ascertaining the subject matter encompassed within the scope of appealed claim 17. The purpose of § 112, second paragraph, was stated in *In re Hammack*, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970) to be:

> to provide those who would endeavor, in future enterprise, to approach the area circumscribed by the claims of a patent, with the adequate notice demanded by due process of law, so that they may more readily and accurately determine the boundaries of protection involved and evaluate the possibility of infringement and dominance.

Therefore, the rejection of claim 17 under 35 U.S.C. § 112, second paragraph, is sustained.

CONCLUSION

To summarize, the decision of the examiner (I) to reject claim 17 under 35 U.S.C. § 112, second paragraph, is affirmed, (II) to reject claims 11, 19 and 20 under 35 U.S.C. § 102 as anticipated by Al-Sioufi is reversed, (III) to reject claims 11, 19 and 20 under 35 U.S.C. § 102 as anticipated by or, in the alternative under 35 U.S.C. § 103 as unpatentable over Fisher is reversed, (IV) to reject claims 11 and 18-20 under 35 U.S.C. § 102 as anticipated by or, in the

alternative under 35 U.S.C. § 103 as unpatentable over Engel '434 is reversed, and (V) to reject claims 11 and 18-20 under 35 U.S.C. § 103 as unpatentable over Wyka is sustained as to claim 20 and reversed as to claims 11, 18 and 19.

Pursuant to the provisions of 37 C.F.R. § 1.196(b), the following new ground of rejection has been made. Claims 11 and 17-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 C.F.R. § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 C.F.R. § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 C.F. R. § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within two months from the date of the original decision ... .

37 C.F.R. § 1.196(b) also provides that the appellant, *WITHIN TWO MONTHS FROM THE DATE OF THE DECISION*, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 C.F.R. § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner ... .

> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record ... .

Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 C.F.R. § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for reconsideration thereof.

OTHER MATTERS

In the event of further prosecution, both appellants and the examiner should consider whether "such opening" as recited in claims 11 and 20 should be --said opening-- for proper antecedent basis.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART; 37 CFR § 1.196 (b)

JOHN D. SMITH
Administrative Patent Judge

BRADLEY R. GARRIS
Administrative Patent Judge

CAROL A. SPIEGEL
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS
) AND
) INTERFERENCES

CAS/sld

Appeal No. 1996-0857
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